

# EXPERT PANEL REVIEW OF PHTHALATES

NTP Center for the Evaluation of Risks to Human Reproduction

FACTSHEET

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In line with the National Toxicology Program's goal to provide toxicological evaluation on substances of public health concern, the NTP and the National Institute of Environmental Health Sciences established the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) to provide scientifically based, uniform assessments of the evidence for reproductive and developmental toxicity of man-made or naturally occurring chemicals or chemical mixtures. The first major step in the Center's evaluation of seven phthalate esters was completed in Arlington, Virginia, on July 12-13 when an expert panel concluded their deliberations on the phthalates. Phthalate esters are used as plasticizers in a wide range of polyvinyl chloride-based consumer products. These phthalate esters were selected for the initial evaluation by the CERHR based on their high production volume extent of human exposures, use in children's products, or published evidence of reproductive or developmental toxicity.

## Expert Panel's Findings

The panel's deliberations focused on the amount and quality of data available in two primary areas, human exposures to these phthalates and experimental evidence for their reproductive and developmental toxicity. Working over a 15 month period, the panel assigned "low, minimal, or negligible concern" for five of the following agents and higher concern for only one, di (2-ethylhexyl) phthalate or DEHP.

For **di(2-ethylhexyl) phthalate** (used in building products, food packaging, children's products and medical devices) there was "serious concern" for the possibility of adverse effects on the developing reproductive tract of male infants exposed to very high levels of DEHP that might be associated with intensive medical procedures such as those used in critically ill infants. The Panel recognized the health benefits of these procedures. There was "concern" that exposure of pregnant women to current estimated adult exposure levels of DEHP might adversely affect the development of their offspring. The Panel expressed "concern" that, if infants and toddlers are exposed to levels of DEHP substantially higher than adults, adverse effects might occur in the developing male reproductive tract. The Panel expressed "minimal concern" that current exposures of adults to DEHP would adversely affect the reproductive system.

For **di-isononyl phthalate** (used in garden hoses, shoes/shoe soles, toys, construction materials), the Panel expressed "minimal concern" for adverse developmental outcomes resulting from exposure of pregnant women and "minimal concern" for adverse effects on the reproductive system of exposed adults. There was "low concern" for potential developmental and reproductive health effects in children who might be exposed to DINP through the mouthing of toys or other DINP-containing objects.

The Panel expressed "minimal concern" for the potential developmental effects that might result from exposure of pregnant women or children to **di-isodecyl phthalate** (used in automobile undercoating, wires and cables, shoes, carpet backing, pool liners). Likewise, there was "minimal concern" for effects on the reproductive systems of adults exposed to DIDP.

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For **di-n-butyl phthalate** (substances used in latex adhesives, cellulose plastics and solvent for dyes), the Panel expressed "minimal concern" for potential effects on human development, including effects on the developing male reproductive tract, and "negligible concern" for effects on the reproductive systems of exposed adults.

The data available on **butyl benzyl phthalate** (used in vinyl tile, food conveyor belts, artificial leather, traffic cones) led the Panel to express "negligible concern" for effects on adult male reproduction. Developmental effects were noted but conclusions could not be drawn.

For **di-n-octyl phthalate** (used in the manufacture of flooring and carpet tile, canvas tarps, notebook covers) the panel expressed "negligible concern" for effects on the human reproductive system and "minimal concern" for adverse developmental effects resulting from exposure during pregnancy or childhood.

There were too few data available on **di-n-hexyl phthalate** (used in automobile parts, tool handles, dishwasher baskets, flooring, tarps, flea collars) for the Panel to reach any conclusions.

### **Report Completion and Distribution**

The Expert Panel Reports on seven phthalates were made available for a 60-day public comment period on October 10, 2000. The comment period ended December 1, 2000. The phthalate reports remain available on the CERHR web site (<http://cerhr.niehs.nih.gov>). As part of its own report, the NTP will transmit the Expert Panel conclusions, the public comments received on the Expert Panel Reports, and any newly available information since completion of the expert panel reports to the appropriate Federal and State Agencies, the public and the scientific community. A special effort will be made to prepare the summary in language that can be understood by those who are not scientifically trained.

*Nominations, requests for expert panel reports and requests for further information should be forwarded to:*

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